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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,358	06/23/2005	Christian Bruns	ON/4-32839A	3326

1095 7590 11/07/2006

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/540,358

Applicant(s)

BRUNS ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060111</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The “particularly...” phrases in claims 6 and 7 and the “e.g., ...” phrase in claim 8 are indefinite. It is not clear if the methods of claims 6 and 7 are limited to improving cardiorespiratory function or airflow in upper airways during sleep, or if the methods embrace improving cardiorespiratory function or airflow in upper airways at any time. It is not clear if the method of claim 8 is limited to promoting paradoxical sleep in elderly subjects, or if the method embraces promoting paradoxical sleep in any subject. It is suggested that the phrases in question could be deleted and made the subject matter of appropriate dependent claims.

2. Claims 6-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 6-9 are improper dependent claims because they recite methods or compositions which can be practiced without infringing independent claim 5, upon which claims 6-9 depend. See MPEP 608.01(n)(III). For example, claim 6 embraces treating subjects to improve cardiorespiratory function where the subjects do not have sleep apnea, and thus the method of claim 6 can be practiced without infringing the independent claim, which requires the subjects to have sleep apnea. Claim 9 recites pharmaceutical compositions which are not required to be used to treat sleep apnea in subjects, and thus the pharmaceutical composition of claim 9 can be practiced without infringing the independent claim.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. *Joy Technologies Inc. v. Quigg*, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. *In re Hoeschele*, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976); *In re Thompson*, 192 USPQ 275, 277 (CCPA 1976).

4. Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 97/01579. The WO Patent Application '579 teaches pharmaceutical compositions comprising somatostatin analogs of the formula recited in Applicants' claim 5. See, e.g., claims 1 and 9 of the reference. To the extent that claim 9 might be amended to recite an intended use

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limitation, note that intended use limitations do not impart patentability to product claims where the product is otherwise anticipated by the prior art.

5. Claims 5-7 and 9 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 03/037256 in view of the Reubi et al article (Eur. J. Pharmacol., Vol. 456, pages 45-49). The WO Patent Application '256 teaches treating sleep apnea, asthma, and disorders affecting the respiratory system, by administering a somatostatin agonist, including agonists of somatostatin receptor types 2 and 5. See, e.g., the Abstract; page 1, second paragraph; page 2, first full paragraph; page 9, third full paragraph; page 10, last paragraph, through page 14; and claims 67 and 74. The WO Patent Application '256 does not teach administering one of the specific somatostatin analogues recited in Applicants' claims. The Reubi et al article teaches the somatostatin agonist KE 108, which is an agonist for all five somatostatin receptors and is stable for several hours in human serum. See, e.g., the Abstract. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the KE108 of the Reubi et al article as the somatostatin agonist of the WO Patent Application '256, because the WO Patent Application '256 is not limited to any particular somatostatin agonist, because the KE108 of the Reubi et al article has the somatostatin agonist activity required by the WO Patent Application '256, and because the serum stability disclosed for KE108 indicates that it can be successfully administered in vivo.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 03/037256 in view of the Reubi et al article (Eur. J. Pharmacol., Vol. 456, pages 45-49) as applied against claims 5-7 and 9 above, and further in view of Jones et al (U.S. Patent Application Publication 2003/0170222), Danguir (Neurobiology of Aging, Vol. 10, pages 367-

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369), and Danguir (Brain Research, Vol. 367, pages 26-30). The WO Patent Application '256 and the Reubi et al article suggest administering the somatostatin agonist KE108 in order to treat sleep apnea, but do not teach or suggest what if any effect this might have on the paradoxical sleep of the subject being treated. Jones et al teach that somatostatin is known to increase REM sleep. See paragraph [0028]. Danguir (Neuro. Aging) teaches that the somatostatin agonist SMS 201-995 is known to promote paradoxical sleep in aged rats. Danguir (Brain Res.) teaches that somatostatin infusions are known to increase paradoxical sleep in rats. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made in the method of the WO Patent Application '256 as modified above by the Reubi et al article that administration of the KE108 would have the effect of promoting paradoxical sleep in the subject being treated, because Jones et al, Danguir (Neuro. Aging), and Danguir (Brain Res.) teach that somatostatin and the somatostatin agonist SMS 201-995 are known to have this effect, and because KE108, which is also a somatostatin agonist, would have been expected to have similar effects on the paradoxical sleep of the subject.

7. Claims 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 03/037256 in view of the WO Patent Application 02/10192. The WO Patent Application '256 teaches treating sleep apnea, asthma, and disorders affecting the respiratory system, by administering a somatostatin agonist, including agonists of somatostatin receptor types 2 and 5. See, e.g., the Abstract; page 1, second paragraph; page 2, first full paragraph; page 9, third full paragraph; page 10, last paragraph, through page 14; and claims 67 and 74. The WO Patent Application '256 does not teach administering one of the specific somatostatin analogues recited in Applicants' claims. The WO Patent Application '192 teaches the

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somatostatin agonist recited in instant claim 10, which is an agonist especially for somatostatin receptors types 2 and 5. The agonist is used pharmaceutically. See, e.g., the Abstract; page 9, table; and page 10, first, second, and third full paragraphs. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the somatostatin agonist of the WO Patent Application '192 as the somatostatin agonist of the WO Patent Application '256, because the WO Patent Application '256 is not limited to any particular somatostatin agonist, because the somatostatin agonist of the WO Patent Application '192 has the somatostatin agonist activity required by the WO Patent Application '256, and because the pharmaceutical uses disclosed for the somatostatin agonist of the WO Patent Application '192 indicate that it can be successfully administered in vivo.

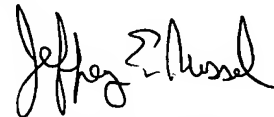
8. Claim 8 is rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 03/037256 in view of the WO Patent Application 02/10192 as applied against claims 5-7 and 10 above, and further in view of Jones et al (U.S. Patent Application Publication 2003/0170222), Danguir (Neurobiology of Aging, Vol. 10, pages 367-369), and Danguir (Brain Research, Vol. 367, pages 26-30). The WO Patent Application '256 and the WO Patent Application '192 suggest administering a somatostatin agonist in order to treat sleep apnea, but do not teach or suggest what if any effect this might have on the paradoxical sleep of the subject being treated. Jones et al teach that somatostatin is known to increase REM sleep. See paragraph [0028]. Danguir (Neuro. Aging) teaches that the somatostatin agonist SMS 201-995 is known to promote paradoxical sleep in aged rats. Danguir (Brain Res.) teaches that somatostatin infusions are known to increase paradoxical sleep in rats. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made in the method of the WO

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Patent Application '256 as modified above by the WO Patent Application '192 that administration of the somatostatin agonist would have the effect of promoting paradoxical sleep in the subject being treated, because Jones et al, Danguir (Neuro. Aging), and Danguir (Brain Res.) teach that somatostatin and the somatostatin agonist SMS 201-995 are known to have this effect, and because the somatostatin agonist of the WO Patent Application '192, which is functionally equivalent to the somatostatin and SMS 201-995 of Jones et al, Danguir (Neuro. Aging), and Danguir (Brain Res.), would have been expected to have similar effects on the paradoxical sleep of the subject.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

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JRussel
October 31, 2006